Objectives

This study aimed to evaluate clinical and laboratory parameters in two groups of inpatients diagnosed with COVID-19. The control group received conventional therapy and the study group treated with conventional therapy as well as the intervention treatment. Different variables such as mortality ratio, hospitalization duration, intensive care unit (ICU) admission, O2 saturation, and different laboratory data (such a lymphocyte count) were assessed between the groups.

Study design and method

This randomized controlled parallel clinical trial was performed in a COVID-19 special hospital in Kermanshah, Iran. Inpatients individuals older than 10 years old with a confirmed diagnosis of COVID-19 according to the SARS-CoV-2 real-time polymerase chain reaction (RT-PCR) and/or lungs computed tomography (CT) scan would be evaluated for further assessments. The exclusion criteria were defined as pregnancy, and chronic liver disease. Patients who met both the inclusion and exclusion criteria, allocated into the two study groups through simple randomization method. The variables mentioned in the objectives were assessed between the two groups. Also, the patients followed for 2 weeks after discharge. Fever was defined according to the guidelines by the Centers for Disease Control and Prevention (CDC) and the Iranian Ministry of Health and Medical Education as body temperature of >38°C and 37.8°C respectively. Acute respiratory distress syndrome defined according to the Berlin definition. The severe COVID-19 was defined according to the National Institute of Health (NIH) definition.

Ethics

The aims and methods of this study clearly explained for patients or their legal guardians (in case of being less than 18-year-old) according to their level of knowledge and they were asked to sign

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a consent form freely following the explanations. This study was approved by the Medical Ethics Committee of Kermanshah University of Medical Sciences. Also, it has been recorded in the Iranian Registry of Clinical Trial (IRCT20150623022884N3) and clinicaltrials.gov (NCT04392141). All the authors adhered to the Helsinki 1964 Declaration and its further revisions.